UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/731,499	10/16/96	GRAY J	2500.124US1

020227 HM12/0621
MAJESTIC PARSONS SIEBERT & HSUE
SUITE 1100
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4106

EXAMINER	
JOHNSON, N	
ART UNIT	**PAPER NUMBER**
1642	31

DATE MAILED: 06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/731,499	Gray
Examiner	**Group Art Unit**
Nancy Johnson	1642

☒ Responsive to communication(s) filed on *Mar 20, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 6-19, and 23-63* is/are pending in the applicat

Of the above, claim(s) *24-44* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 6-19, 23, and 45-63* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 2-5, 20-22 have been canceled.

Claims 47-63 have been added.

Claims 1, 6-19 45 have been amended. 46 has been added.

Claims 1, 6-19, 23-63 are pending.

Claims 24-44, drawn to non-elected inventions, are withdrawn from examination.

Claims 1, 6-19, 23 and 45-63 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claim 45 under 35 U.S.C. 112, first paragraph, as new matter is withdrawn.

4. The rejection of claims 1, 6-7, 10-17, 45-61, 63 under 35 U.S.C. 112, second paragraph, is withdrawn. The rejection of claims 8, 9, 18, 19, 60-62 under 35 U.S.C. 112, second paragraph, is made and maintained.

Rejections based on the recitation "specifically hybridizes" and "subsequence" are withdrawn.

Rejection of claims 1, 6, 10, 12, 14, 16 and 18 for the recitation "stringent conditions"are withdrawn, in view of amendment of claim 1 to recite specific hybridization conditions and the amendment of claims 6, 10, 12, 14, 16 and 18 to recite "said stringent conditions.".

Claims 8, 60 and 61 remain vague and indefinite in the recitation "hybridizes under stringent conditions" and or "hybridizes." Absent limitations directed setting forth specific stringency conditions (temperature and salt concentration), the metes and bounds of nucleic acid sequences hybridizing under "stringent conditions" is unknown. Applicant is advised to amend the claims to recite "said stringent conditions."

Newly amended claim 18 is vague and indefinite in the recitation "the nucleic acid of 45." Is this claim to depend from claim 1 or claim 45?

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 1-2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 23 and 46 under 35 U.S.C. 102(b) as being anticipated by the 1994-1995 Promega Catalog is withdrawn.

7. The rejection of claim 22 under 35 U.S.C. 102(b) as being anticipated by the 1993/94 New England Biolabs Catalog is withdrawn.

8. The rejection of claims 1, 6, 23, 45-46 under 35 U.S.C. 102(a) as being anticipated by any of Accession Numbers N32481 (10 Jan 1996), N93893 (05 April 1996) or G11697 (19 Oct 1995) is withdrawn.

9. Claims 1, 6, 23 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Accession Numbers N32481 (10 Jan 1996), N93893 (05 April 1996) or G11697 (19 Oct 1995) in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:4 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the

polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

10. The rejection of claims 1, 8, 23 and 45-46 under 35 U.S.C. 102(b) as being anticipated by any of Accession Numbers H16953 (29 June 1995), 16954 (29 June 1995) or H12950 (27 June 1995) is withdrawn.

11. Claims 1, 8, 23 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Accession Numbers H16953 (29 June 1995), 16954 (29 June 1995) or H12950 (27 June 1995) in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:5 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so

with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

12. The rejection of claims 1, 10, 23 and 45-46 under 35 U.S.C. 102(a) as being anticipated by Accession Number H40682 (16 Aug 1995) is withdrawn.

13. Claims 1, 10, 23 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession Number H40682 (16 Aug 1995) in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:5 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

14. The rejection of claims 1, 12, 23 and 45-46 under 35 U.S.C. 102(a) as being anticipated

by either of Accession Number G27410 (28 June 1996) or G25553 (31 May 1996) is withdrawn.

15. Claims 1, 12, 23, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Accession Number G27410 (28 June 1996) or G25553 (31 May 1996) in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:7 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

16. The rejection of claims 1, 14, 23, 45-46 under 35 U.S.C. 102(a) as being anticipated by Accession Number N78571 (29 March 1996) is withdrawn.

17. Claims 1, 14, 23, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession Number N78571 (29 March 1996) in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences

that would hybridize to SEQ ID NO:8 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

18. The rejection of claims 1, 16, 18, 23, 45-46 under 35 U.S.C. 102(a) as being anticipated by Accession Number N70546 is withdrawn.

19. Claims 1, 16, 18, 23, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession Number N70546 in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:9 or SEQ ID NO:10 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of

ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

20. The rejection of claims 1, 18, 23 45-46 under 35 U.S.C. 102(a) as being anticipated by Accession Number WO5407 is withdrawn.

21. Claims 1, 18, 23, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession Number WO5407 in view of Matthews and Kricka (Analytical Biochemistry 169:1-25, 1988). The cited Accession Numbers teach polynucleotide sequences that would hybridize to SEQ ID NO:10 under stringent conditions. The cited Accession Number do not teach such polynucleotide sequences that are labeled. However, Matthews and Kricka teach methods for the labeling of polynucleotide sequences with various detectable labels (see Tables 2-4) for use as a probe in a wide range of methods, such as the mapping of the position of a DNA sequence relative to restriction enzyme sites and the quantitation of a specific RNA or DNA sequence in a sample (see p. 1). It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to label the polynucleotide sequences taught by the Accession Number, by the methods taught in Matthew and Kricka, for use as probes in the further characterization of the polynucleotide sequences of the Accession Numbers, such as restriction mapping of the Accession Number polynucleotide or the detection of mRNA transcripts expressing said Accession Number polynucleotide sequences. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of

Matthews and Kricka, that the labeling of polynucleotide sequence and the use of these labeled sequences as probes is routinely done for the further characterization of a polynucleotide sequence (such as each Accession Number).

22. 1, 6-19, 45-46, 58-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 6, 8, 10, 12, 14,16, 18, 45-46, 58-61 and 63 are drawn to isolated nucleic acid molecules comprising a polynucleotide sequence that hybridizes under defined high stringency conditions to a sequence selected from the group consisting of SEQ ID NO:2-10 and 12. Thus, the claims are drawn to a large genus of polynucleotides, those that hybridize to SEQ ID NO:2-10 or 12. This includes not only each SPECIFIC disclosed sequence (of SEQ ID NO:2-10 and 12, but also the polynucleotide sequences that embrace a wide range of substitution, insertion or deletion changes throughout the entire stretch of nucleotides found in the reference SEQ ID NO: and also the gene that encodes these polynucleotide sequences. The specification demonstrates reduction to practice of only a single species for each genus, SEQ ID NO:2-10 and 12. The specification provides no disclosure of any of the elements of a gene of the characterization of any mutations. For adequate written description, all of these elements must be described. molecules. Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

23. The provisional rejection of claims 3, 5, 7, 9, 11, 13 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of U.S. Patent No. 5,892,010 is withdrawn.

24. The provisional rejection of claims 1, 6-13, 23, 45-53, 58-60 and 63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of

U.S. Patent No. 5,892,010 is made and maintained.

25. The provisional rejection of claims 1, 6-19, 23 and 45-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over non-elected claims 1-21 and 25-29 of copending Application No. 08/785,532 is made and maintained.

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 7, 9, 11, 13 are rejected under the judicially created doctrine of double patenting over claim 8 of U. S. Patent No. U.S. Patent No. 5,892,010 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: An isolated nucleic acid molecule comprising a labeled polynucleotide sequence comprising SEQ ID NO:4 (claim 7), SEQ ID NO: 5 (claim 9), SEQ ID NO:6 (claim 11) or SEQ ID NO:7 (claim 13). Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

June 19, 2000